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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/031,396

02/22/2002

Junichi Miyazaki

2002-0053

2281

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7590

05/16/2006

WENDEROTH, LIND & PONACK, L.L.P.

2033 K STREET N. W.

SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,396

Applicant(s)

MIYAZAKI ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 February 2006 has been entered.

Claims 1- 4, and 9- 11 are under consideration in this action.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1- 4 and 9- 11 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended the claims to clarify the term "outer sequence" and the wording of E1 or E1 and E2.

Rejections Maintained

Claim Rejections - 35 USC § 103

Claims 1- 4 and 9- 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graham, Fu *et al.*, and Chen *et al.*

Applicant argues that the cited references fail to disclose or teach the recited sizes of the structural components, that Graham has two limitations (low efficiency and virus size), that Chen *et al.* fail to disclose the structural elements, and that Fu *et al.* is impractical.

Applicant's arguments have been fully considered and not found persuasive.

Graham teaches the invention essentially as claimed.

Graham teaches a plasmid based vector that can be used to make an infectious adenovirus with an E1 deletion (Figure 1). Graham teaches that plasmids are more efficient for manipulating adenovirus than live virus but there may be stability problems (page 2921, last paragraph). Graham teaches that Ad5 can accommodate about 2kb extra of DNA (Figure 1 caption).

Graham does not teach cosmids or recombinase sites.

Fu *et al.* teach that cosmids are able to handle the large size of adenoviral DNA, and that they work in bacteria (page 1322, column 1 last paragraph to last paragraph on same page). This also includes that the cosmid sequence is about 5Kb and this is about 7Kb as claimed.

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Chen *et al.* teach that recombination systems (Cre-lox) have been extensively used for the manipulation of DNA (page 477 first paragraph).

One of ordinary skill in the art at the time of invention would have known about E1 and E3 deletion and insertions into the a region for expression are well known in the art. It is well known in the art as noted by Graham that Ad5 is 36kb and can take 2kb (see above) extra DNA and still be packaged. The size of E1 and E3 are known as well and one of skill in the art could approximate the size of viral vectors and inserts recited in the claims. One of ordinary skill in the art at the time of invention would have known the size of the cosmid sequence is limited for packaging in phage and that the size of this insert is flexible as long as the size limits of the phage or Ad particle is not exceeded.

One of skill in the art at the time of invention would have been motivated to start vector manipulation using the vector of Graham which has all the inserted DNA in the E1 region deletion.

One of skill in the art at the time of invention would have known that cosmids could be used as a "plasmid" to carry a large insert. One of ordinary skill in the art would have been motivated to modify the plasmid of Graham because of the strength of the cosmid system as taught by Fu *et al.*

Thus, it would have been *prima facie* obvious to modify the vector of Graham with the cosmid and recombinase to make the vector as claimed with the expectation of success in making an adenoviral vector with an expression cassette inserted into a

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deletion of the E1 and or the E3 region knowing that cosmids are taught to efficiently construct adenovirus *in vitro* and the recombinase system is useful for deleting unneeded sequences from DNA.


Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Myron G. Hill
Patent Examiner
8 May 2006



BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600